

## **5 510(k) Summary**

Terumo BCT requests that the attached “Summary” for the Spectra Optia Apheresis System be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this 510(k) submission.

## **510(k) Summary**

### **I. SUBMITTER**

Terumo BCT, Inc.  
10811 W. Collins Avenue  
Lakewood, Colorado 80215  
Phone: 877-339-4228  
Fax: 303-231-4756

Contact Person: Ashley Davis  
Title: Regulatory Affairs Specialist  
Date Prepared: 04-17-2015

### **II. DEVICE**

Trade Name of Device: Spectra Optia® Apheresis System  
Common or Usual Name: Apheresis Device or System  
Classification Name: Automated Blood Cell Separator  
Regulatory Class: In accordance with 21 CFR 864.9245(b), the classification for this device is Class II with special controls.  
Product Code: GKT

### **III. PREDICATE DEVICE**

**Table 1: Predicate and Reference Device Information**

<b>Device</b>	<b>Product Classification</b>	<b>Trade Name Of Predicate Device</b>	<b>Manufacturer and 510(k) Holder</b>	<b>510(k) Clearance Number</b>
Predicate	GKT	COBE® Spectra Apheresis System	Terumo BCT	BK940016
Reference	GKT	Spectra Optia Apheresis System – PMN Collection Procedure	Terumo BCT	BK130065

### **IV. DEVICE DESCRIPTION**

#### **A. Device Identification**

The Spectra Optia Apheresis System is a centrifugal system designed to separate whole blood to remove cellular or plasma components from the blood of donors and patients and has been cleared to conduct Therapeutic Plasma Exchange (TPE) procedures (K071079). Terumo BCT, Inc. has developed a Continuous MNC Collection (CMNC) Protocol for implementation on the Spectra Optia® Apheresis System. This additional protocol represents an enhancement to the platform's overall utility and functionally equivalent to the protocol conducted on the predicate COBE Spectra Apheresis System.

The Spectra Optia Apheresis System is an automated centrifugal system that separates whole blood into its cellular and plasma components. The device is comprised of three major subsystems, (1) the apheresis machine itself (centrifuge, centrifuge filler, pumps, valves, computerized safety and control systems, etc.), (2) sterile, single-use, disposable blood tubing sets and, (3) embedded software. The CMNC Protocol is implemented using a new IDL tubing

sets, catalog number 10310, and the currently released software. The Spectra Optia system will be configured as follows (Table 2):

**Table 2: Configuration of Spectra Optia® Apheresis System Device by Subsystem**

	Subsystem	CMNC Procedure	Described in 510(k) Submission
<b>1</b>	Apheresis Machine	Catalog No. 61000	No Cleared under K071079
	Centrifuge Filler (component of apheresis machine)	IDL Filler	No Cleared under BK130065
<b>2</b>	Disposable Tubing Sets	IDL Tubing Set, Catalog No. 10310	Yes
<b>3</b>	Embedded Software	Version 11.2	No Cleared under BK140191

## **B. Device Characteristics**

### **Spectra Optia Apheresis System**

The Spectra Optia system (also referred to as hardware or equipment) that will be used to conduct the CMNC Protocol is functionally equivalent to the machine that is FDA cleared for the conduct of Therapeutic Plasma Exchange (TPE). The machine consists of an automated centrifugal, blood-cell, separation device that uses pumps, valves and sensors to control and monitor the extracorporeal circuit, during therapeutic apheresis or cell collection procedures. Since the Spectra Optia Apheresis System was first cleared by CDRH for commercial use, there have been no significant changes to the system's hardware. There have been no modifications to the Spectra Optia to support the CMNC Protocol.

### **Spectra Optia IDL Tubing Set**

The IDL tubing set, catalog number 10310, is comprised of the same biocompatible materials as in the FDA-cleared IDL tubing set, catalog number 10300, and is generally manufactured, packaged and ethylene oxide (EtO) sterilized in the same way.

### **IDL Filler**

The separation geometry in the Spectra Optia Apheresis System, and in all Terumo BCT, Inc. apheresis devices, is controlled by the Centrifuge Filler. The disposable tubing set's separation channel is loaded into the filler during system setup. During the apheresis procedure, and while the filler is spinning, the separation channel fills with blood and expands to fit the space provided by the filler. In this way, the filler defines the separation geometry without touching the donor or patient's blood. The IDL Filler, and not the standard Optia filler, is used in the CMNC protocol because the geometry of the channel allows for the optimal blood separation for collection of MNCs.

### **Spectra Optia Apheresis System Software, Version 11.2**

The CMNC Protocol is already an embedded module within system software Version 11.2. The version 11.2 software was cleared by FDA in BK140191. All the currently developed protocols are resident on the permanent disk, but only the protocols for which the machine has been configured for are presented to the user for selection. Machine configuration requires software

tools only licensed to qualified service personnel ensuring that only approved protocols are available to the operator.

**Anticoagulant Connector**

Also described in this 510(k) is a new Anticoagulant (AC) connector on the Spectra Optia Apheresis System's disposable tubing sets. Terumo BCT has proactively changed the AC connector on the Spectra Optia Apheresis System's disposable blood tubing sets from a standard spike to a specialized luer that is not compatible with any other connection on the set. The AC connector is used by operators to attach a bag of anticoagulant ACD-A to the Spectra Optia system. Terumo BCT is modifying the ACD-A solutions sets manufactured at Terumo BCT Larne, UK from a tubing line with a spike receptor port to a luer connection and in-line frangible above the port. Customers can also source ACD-A solution from other manufacturers. To facilitate customer transition to the new luer connection, an AC Connection Adapter is being provided in order to connect the tubing sets containing the new AC luer connector to ACD-A solution sets with a spike port.

**C. Environment of Use**

The CMNC Protocol is performed in a hospital or clinic environment.

The operation of the Spectra Optia system for CMNC protocol is performed by professionally-trained apheresis operators. Operators are commonly trained on the principles of apheresis by their organization. Operators of the device have a variety of backgrounds and professional training, and the primary users are expected to be nurses or laboratory technicians.

**D. Device Description**

During a CMNC procedure on the Spectra Optia system, mobilized and anticoagulated whole blood undergoes a separation procedure in which MNCs are continuously removed by means of centrifugal sedimentation and selective collection of the density layer rich in MNCs. The density layer collected has low red platelet content due to the low packing factor used in the procedure. The skimmer dam at the connector allows for the targeted cells to accumulate at the collect port and discourages red blood cells and granulocytes from accumulating at the collect port helping create a low red blood cell product as well.

The purpose of the Spectra Optia CMNC protocol is to provide COBE Spectra-like performance and design with which operators are familiar, while offering automation and advanced Spectra Optia features. Functional equivalence is supported by commonalities in intended use, essential technology (i.e., the separation of blood components by centrifugation) and, the outcomes of both the laboratory and clinical studies.

The electrical power requirements for the Spectra Optia are 10-4 Amps and 50/60Hz with 100-240 Vac.

**E. Materials of Use**

Since Terumo BCT, Inc. has obtained clearance for the Apheresis Machine (K071079), and the IDL Filler (BK130065), the discussion of materials of use is limited to the IDL tubing set, catalog number 10310, the IDL tubing set, catalog number 12320, the Collection tubing set, 12120, and Anticoagulant (AC) Connection Adapter, catalog number 11221. The IDL tubing set,

catalog number 10310, the IDL tubing set, catalog number 12320, the Collection tubing set, 12120, and Anticoagulant (AC) Connection Adapter, catalog number 11221 makes use of existing materials that are used in several different marketed product lines, including COBE Spectra and Spectra Optia. These materials include plasticized polyvinyl chloride (PVC) for tubing, copolyester, acrylonitrile butadiene styrene (ABS), and polycarbonate; these materials are medical grade and are deemed suitable for human blood and blood components. The materials used in the IDL tubing set, catalog number 10310, the IDL tubing set, catalog number 12320, the Collection tubing set, 12120, and Anticoagulant (AC) Connection Adapter, catalog number 11221 that do not make blood contact include low density polyethylene and high density polyethylene.

#### **F. Key Performance Specifications/Characteristics of the Device**

The CMNC Protocol consists of the system recirculating mobilized and anticoagulated whole blood into the IDL tubing set, catalog number 10310, and channel. The channel spins in the centrifuge at high speed to separate the components of the mobilized and anticoagulated whole blood to establish the RBC interface. The automated interface management (AIM) system adjusts the flow rate of the plasma pump to control the concentrations of cells that flow through the collect port thereby maintain the optimum interface position for MNC collection. When cells are first detected in the collect port, the collect valve moves to the collect position and the collect pump pumps the cells into the collection bag. The remaining components are either pumped or passively flow back into the reservoir in the tubing set and are returned to the donor.

#### **V. INTENDED USE**

The Spectra Optia Apheresis System may be used to collect Mononuclear Cells (MNC) from the peripheral blood of patients and blood donors.

#### **VI. INDICATIONS FOR USE**

The Spectra Optia® Apheresis System, a blood component separator, may be used to perform procedures for the collection of mononuclear (MNC) cells from the peripheral blood.

The Indications for Use statement for the Spectra Optia® Apheresis System – CMNC Protocol is not identical to predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

#### **VII. TECHNOLOGICAL COMPARISON**

Spectra Optia system simplifies the CMNC Protocol when compared to the predicate system with the use of on-screen guidance and an integrated cassette tubing set design. The Spectra Optia System key performance characteristics for the CMNC Protocol when compared to the predicate are:

- A Mean Collection Efficiency for CD34+ cells of 84.8% ( $\pm 16.39\%$ ) compared to 66.2% ( $\pm 15.26\%$ )
- A Mean Collection Efficiency for MNCs of 62.9% ( $\pm 17.60\%$ ) compared to 47.0% ( $\pm 10.98\%$ )
- Provides a product volume under 200mL
- Allows operators to perform other tasks during the procedure as the system continuously monitors and adjusts the interface

The technology for the Spectra Optia system is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the collection of mononuclear cells (MNCs).

## **VIII. PERFORMANCE DATA**

The following performance testing was submitted in support of a determination of substantial equivalence between the subject and predicate device. A summary of the performance testing is presented in Table 3 below. Test data demonstrates that the device met all performance requirements and that the subject device is as safe, as effective, and performs as well or better than the predicate device.

**Table 3: Summary of Performance Studies**

<b>Test Name</b>	<b>Purpose of Study</b>	<b>Result</b>
System and Disposables Verification Summary Report for the Spectra Optia CMNC Protocol	To summarize the System and Disposable Verification activities completed for the Spectra Optia CMNC Protocol	Pass
Design Validation for Spectra Optia CMNC	To show that the CMNC Collection Protocol was non-inferior to the COBE Spectra MNC Collection Protocols in terms of MNC and platelet collection efficiencies, and procedure time including plasma collection.	Pass
Design Verification Report for Apheresis Safety AC Connection Project	To summarize the verification testing for the AC Connection project.	Pass

### **A. Mechanical Testing**

A variety of physical and mechanical testing was conducted for the CMNC Protocol, IDL tubing set, catalog number 10310, IDL tubing set, catalog number 12320, the Collection tubing set, catalog number 12120, and Anticoagulant Connection Adapter, catalog number 11221. The results are all passing within acceptance criteria.

Verification and Validation testing has demonstrated that the Spectra Optia CMNC Protocol works as intended, and is substantially equivalent to the predicate device, COBE Spectra MNC Procedure. Bench verification testing consisted of integrated systems testing of the machine, disposables, and software. Bench validation testing was performed over a broad range of operational setting/parameters using blood products that vary with respect to clinical conditions for platelet content and MNC Content.

### **B. Biocompatibility Testing**

The biocompatibility evaluation for the IDL tubing set, catalog number 10310, IDL tubing set, catalog number 12320, the Collection tubing set, catalog number 12120, and Anticoagulant Connection Adapter, catalog number 11221, was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

**C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing**

Comprehensive EMC and Electrical Safety Reports were submitted to FDA as part of K071079. There have been no changes to the Spectra Optia machine or its electronic systems.

**D. Software Verification and Validation Testing**

Software verification and validation testing for Version 11.2 software was conducted and documentation as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and was cleared by FDA in BK140191.

**E. Sterility Testing**

Products are validated to ensure that they are not released until acceptance criteria are met according to the requirements outlined in ANSI/AAMI/ISO 10993-7:2008. When sterilized with the validated ethylene oxide cycle, the product has a sterility assurance level of  $< 10^{-6}$ . When outgassed using the validated process, the IDL tubing set, catalog number 10310, IDL tubing set, catalog number 12320, the Collection tubing set, catalog number 12120, and Anticoagulant Connection Adapter, catalog number 11221, meet the residual limits according to predetermined acceptance criteria. Product sterilization has been successfully demonstrated and is similar to the Spectra Optia family of disposables.

**F. Stability/Shelf Life Testing**

The shelf life of the IDL tubing set, catalog number 10310, IDL tubing set, catalog number 12320, the Collection tubing set, catalog number 12120, and Anticoagulant Connection Adapter, catalog number 11221, was determined to be 2 years. Terumo BCT, Inc. evaluated the overall configuration and materials, their packaging and sterilization process.

**G. Clinical Studies**

Clinical testing of the Spectra Optia Apheresis System Continuous MNC Collection (CMNC) Protocol included a pivotal study of 23 patients. Substantial equivalence was based in part on the clinical study.

**Pivotal Study**

Terumo BCT conducted a prospective, randomized, open-label, crossover, multicenter study to evaluate the performance and safety of the Continuous MNC Collection (CMNC) Protocol on the Spectra Optia system as compared to the Mononuclear Cell (MNC) collection procedure on the COBE Spectra system in a representative population of 23 healthy blood donors receiving granulocyte-colony stimulating factor for MNC mobilization.

***Location of Study***

The study was conducted at 2 sites in the United States: Hoxworth Blood Center in Cincinnati, Ohio, and Key Biologics, LLC in Memphis, Tennessee.

***Primary effectiveness endpoint***

The primary effectiveness endpoint was the CD34+ cell collection efficiency (CE1%) which was defined as the target cells collected as a percentage of the target cells available in the total blood volume (TBV) processed.

### ***Secondary Effectiveness endpoints***

The secondary effectiveness endpoints included the following:

1. CD34+ collection efficiency (CE2 %)
2. MNC collection efficiency (CE1 and CE2 %)
3. CD34+ per kg of body weight
4. MNC product contamination/purity (%)
  - a. Red blood cell content / hematocrit ( $10^6$  / $\mu$ L)
  - b. Granulocyte content ( $10^3$  / $\mu$ L)
  - c. Platelet content ( $10^3$  / $\mu$ L)
  - d. Platelet collection efficiency (CE1 %)
5. Product volume (mL)
6. Purity of plasma collected for laboratory processing of MNC product
  - a. Platelet concentration in concurrent plasma ( $10^3$  / $\mu$ L)
7. Procedure time (minutes)

### ***Safety***

The study reported 23 patients with a total of 0 serious adverse events (SAEs).

**Table 4: Patient Accountability**

Stage	Lead-In	Treatment Assignment Number 1	Treatment Assignment Number 2	Total
Enrollment	1	12	10	23
Treatment	1	12	10	23
Primary Effectiveness Endpoint Analysis	*	12	10	22
Secondary Effectiveness Endpoint Analysis	*	12	10	22
Safety Evaluations	1	12	10	23

\*The Lead-In subject was not part of the Intent to Treat (ITT) population and therefore not included in the Effectiveness Analysis. The Lead-In subject was included as part of the safety population.

Regarding device performance, the primary endpoint of the study was achieved, and the CMNC protocol on the Spectra Optia was shown to be non-inferior to the MNC collection protocol on the COBE Spectra. The reported 95% CI (7.78%) and the results of non-parametric ANCOVA testing ( $P < 0.001$ ) both supported non-inferiority. There were no significant period or sequence effects observed for the primary endpoint.

The CMNC collection protocol on the Spectra Optia was generally safe and well tolerated in healthy volunteers. The incidence, frequency, and severity of adverse events (AEs) were similar on the Spectra Optia and the COBE Spectra. There were 22 subjects (95.7%) who reported at least 1 pre-collection treatment emergent AE (TEAE) (38 total events). There were 13 subjects (56.5%) who reported 1 or more TEAEs associated with the Spectra Optia. There were 16 subjects (72.7%) who reported 1 or more TEAEs associated with the COBE Spectra. All TEAEs were considered mild except 2 TEAEs that were moderate severity (bone pain and thrombocytopenia). No SAEs or UADEs were reported. Only 1 device deficiency was reported, and it was not linked to an individual subject. Overall, the safety profiles of the Spectra Optia

and the COBE Spectra apheresis systems in this study were consistent with G-CSF mobilized subjects undergoing leukapheresis.

***Summary***

Results from the study demonstrated that the investigational CMNC protocol on the Spectra Optia was a safe and efficient means of collecting CD34+ cells in MNC mobilized donors. This investigational protocol was statistically non-inferior to the MNC protocol on the COBE Spectra, and several performance and product quality parameters were superior to the COBE Spectra.

**IX. CONCLUSIONS**

Based on the non-clinical and clinical tests performed on the proposed Spectra Optia Apheresis System CMNC Protocol is as safe and effective as the legally marketed predicate device. The information provided in the 510(k) demonstrates that the Spectra Optia Apheresis System CMNC Protocol is substantially equivalent to the identified predicate device.